

Notice of Allowability	Application No.	Applicant(s)	
	09/991,363	DUKE ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response of 12/15/05.
2. ☒ The allowed claim(s) is/are 34-50.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

1. Currently, claims 34-50 are pending in the application.
2. In the prior action, mailed on June 15, 2005, claims 1-25, 29, and 31-33 were pending, with claims 1-3, 8, 9, 11-15, and 29-33 under consideration and rejected; and claims 4-7, 10, and 16-25 withdrawn as to non-elected inventions. In the Response, filed on December 16, 2005, the Applicant cancelled claims 1-25, 29, and 31-33, and added new claims 34-50.
3. In view of the amendments to the claims, claims 34-50 are allowed. Claims 36, 44, 45, 47-50, which correspond to previously withdrawn inventions, are rejoined with the elected invention of claims 34, 35, 37-43, and 46, either as falling within the scope of an allowed linking claim, or a describing a process of making or using the allowed product.

The restriction requirement between restriction groups I-III in the May 2003 restriction requirement (representing the currently pending and allowed inventions) is withdrawn.

Claim Objections

4. **(Prior Objection- Withdrawn)** Claim 15 was objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. In view of the cancellation of this claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

5. **(Prior Rejection- Withdrawn)** Claims 1-3, 8, 9, 11-15, 29, and 31-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Barbera-Guillem (U.S. Pub 2002/0155108) and Paglia et al. (J Exp Med, 183: 317-22) in view of Duke et al. (U.S. Patent

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5,830,463). The previously rejected claims have been cancelled and replaced with corresponding new claims (claims 34, 35, 37-43, and 46) that require that the antigen is heterologous to and not expressed by or loaded into yeast cells. The Applicant asserts that this amendment of the claims overcomes the prior art in that, while the Duke reference teaches the use of antigens expressed by or loaded into yeast cells to active and induce an immune response by DC cells, the reference does not teach that DC cells could also be activated by antigens administered together with, but not expressed or contained by, yeast vehicles. The Applicant asserts that the teachings of the specification have shown that such administration results, wherein the antigens are not within, or part of, the yeast cell, in an unexpectedly improved result over the administration of the antigens alone. In view of the amendments to the claims, and the arguments made pursuant thereto, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 1-3, 8, 9, and 11-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Duke in view of the teachings of Tomai. The Applicant's arguments are found persuasive with respect to the newly presented claims. The rejection is therefore withdrawn.

Conclusion

7. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

Massot et al., FR 2,486,400. This reference teaches the use of certain fungal cells as adjuvants. However, the reference does not teach that such cells would be effective for the activation of DC cells for the uptake and induction of immune responses against antigens.

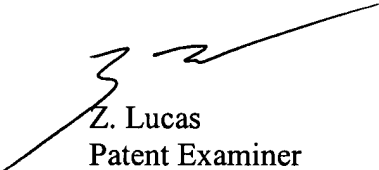
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Brossier et al., Infect Immun 67: 964-67. This reference is considered relevant because the reference establishes that the term "*Bacillus anthracis* protective antigen" is a term of art referring to a specific protein of the *B. anthracis* pathogen. Thus, reference to this antigen in the claims (e.g., claim 36) is not considered an indication of therapeutic or protective effect.

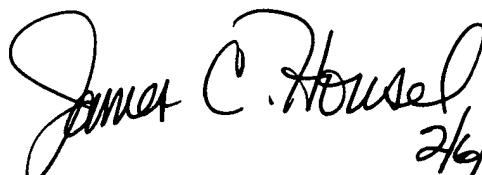
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



2/6/06
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